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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,302	07/19/2001	Roberto A Macina	DEX-0180	6964

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EXAMINER

HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/05/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,302

Applicant(s)

MACINA, ROBERTO A

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed Aug. 11, 2003 is acknowledged. Claims 6-10 were canceled. Claims 1-5 were amended. Claims 1-5 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained:

3. The rejection of claims 1, 3, and 5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained for the reasons of record.

Applicant's arguments have been carefully considered, but fail to persuade. Applicant asserts that the data of Tables 1 and 2 are adequate for demonstrating demonstrate that measuring levels of ESBPIII would be diagnostic of cancer and that one of skill in the art would be able to use the claimed inventions to assess a stage or to monitor a change in stage of gynecologic cancer. Applicant supports this assertion by pointing out that the specification demonstrates that ESBPIII is overexpression in 6 out of 11 samples. However, this argument is not found persuasive because, as pointed to in the previous Office action there is both over expression and

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under expression in the cancerous endometrial samples. It is not the case that in over 50 percent there is over expression and in the other samples there is not change in expression. The difficulty is that there is both over and under expression for the same cancer type. Thus, using the mRNA expression of ESBPIII appears to be an unpredictable basis for a diagnostic test. Applicant also asserts that the specification teaches methods for assessing cancer stage or monitoring a change in stage. However, while the methods are contemplated prophetically, there is no supporting data to establish a relationship between either mRNA levels or protein levels and the diagnostic test endpoints.

With regard to the applicant's arguments concerning the use of mRNA data to establish that detection of the protein product could be used as a basis for a diagnostic test, applicant's reference to one example fails to demonstrate that it would be more likely than not that such a correlation exists in the instant case; whereas the previous Office action established that the relationship between steady state mRNA levels and steady state protein levels appears to be unpredictable.

Because the specification appears to be merely an invitation for further research to establish a correlation between levels of ESBPIII and gynecologic cancer, stage of gynecologic cancer or change in stage of gynecologic cancer, it is unpredictable whether one of skill in the art would be able to practice the claimed invention. Further, because there is no data in the specification demonstrating a correlation between protein levels and gynecologic cancer, the specification fails to establish that measurement of ESBPIII protein levels could be the basis for the claimed methods, it is unpredictable whether one of skill in the art could practice the claimed

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invention to the extent that the claimed inventions comprise methods of measuring ESBPIII levels. Because the relationship between ESBPIII levels and gynecologic cancers has not been established, one of skill in the art would be required to engage in undue experimentation to practice the claimed inventions.

4. The rejection of claims 2 and 4 under 35 U.S.C. 102(e) as being anticipated by Lehrer (Lehrer et al, U.S. Pub. NO.: US 2002/0034739, published March 21, 2002, filing date July 7, 1998) is maintained for the reasons of record.

Applicant argues that Lehrer fails to anticipate the claimed inventions because Lehrer only teaches that prostate cancer cells express lipophilin c and therefore the reference is not enabling for methods of detection of metastases in gynecologic cancers. This argument is not persuasive, because, as Lehrer teaches, the detection of metastases involves the detection of cells that are shed into the bloodstream or other body fluid. Since Lehrer teaches that lipophilin c is expressed in uterus, breast and ovary, Lehrer teaches a method for detection of the metastasis of a gynecologic cancer. Furthermore, it is pointed out that for claim 2, as the claim is currently recited, it reads on the detection of the metastasis of any type of cancer, despite the preamble, because the first step is "identifying a patient having a selected cancer". Thus, the method steps are not restricted to measurements in gynecologic cancers.

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Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
November 3, 2003


ANTHONY C. CAPUTA
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